

September 5, 2002

Mr. Bruce Mabrito, Director
Quality Assurance
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Road, Building 189
San Antonio, TX 78238-5166

SUBJECT: OBSERVATION OF THE JULY 2002 INTERNAL AUDIT OF CENTER FOR
NUCLEAR WASTE REGULATORY ANALYSES

Dear Mr. Mabrito:

From July 23 through 26, 2002, members of the U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards staff participated as observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) Internal Quality Assurance (QA) Audit 2002-1, conducted in San Antonio, Texas. The NRC staff evaluated this audit to determine whether the CNWRA is effectively implementing the requirements of its QA program. This letter transmits NRC Observation Audit Report Number OAR-02-09-CNWRA.

The audit evaluated the adequacy and effectiveness of the CNWRA QA program and its implementation. Eighteen applicable QA programmatic areas and seven technical areas were audited. The technical areas included: 1) Licensing Support Network; 2) Container Life and Source Term; 3) Repository Design and Thermal Mechanical Effects; 4) Mixed Oxide Fuel Fabrication Facility Technical Assistance; 5) Reuse Soil Scenario Analysis; 6) Integrated Issue Resolution Status Report; and 7) Total System Performance Assessment and Technical Integration. This report addresses the effectiveness of the audit and the procedural adequacy and effectiveness of implementation of QA programs controls in the audited areas.

The NRC observers (hereafter, observers) based their evaluation of the audit process and the CNWRA QA program on: 1) discussions with, and direct observations of: a) the audit team, and b) CNWRA staff being audited; and 2) reviews of pertinent audit documentation, such as the audit plan, the audit checklist, CNWRA deliverables, and other CNWRA documents. The observers determined that, overall, CNWRA Audit 2002-1 achieved its purpose, and was thorough, effective, and performed in a professional manner. In general, the observers agree with the audit team's findings and that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated.

During the audit, the audit team identified two major deficiencies in the areas of data interpretation and analysis (Ref: CQAM Section 3.3.10) and verification of calculations (Ref: QAP-014) and one minor deficiency dealing with inconsistency in the frequency for trending adverse conditions (Ref: QAP-010). Also three isolated incidents were identified and corrected during the audit.

B. Mabrito

-2-

The observers discussed their observations with the audit team and CNWRA management during the conduct of the audit and at the post-audit meeting.

We will continue to monitor the CNWRA progress in correcting its QA-related problems. Although a written response to this letter or the enclosed report is not required, we request that the CNWRA provide us with copies of its response to the audit team's findings. If you have any questions, please call Ted Carter at (301) 415-6684.

Sincerely,
/RA/

Deborah A. DeMarco
NRC CNWRA Deputy Program Manager
Program Management, Policy Development
and Analysis Staff
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-02-09-CNWRA, "Observation Audit of Center for Nuclear Waste Regulatory Analyses"

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U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. OAR-02-09-CNWRA,
"OBSERVATION AUDIT OF THE
CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
AUDIT 2002-1"

 /RA/ Date: 08/22/02

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Enclosure

1.0 INTRODUCTION

From July 23-26, U. S. Nuclear Regulatory Commission (NRC) staff participated as observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) internal Quality Assurance (QA) Audit 2002-1 conducted in San Antonio, Texas. The NRC staff evaluated this performance-based audit to determine whether the CNWRA is continuing to effectively implement the requirements of its QA program.

The audit evaluated the adequacy and effectiveness of the CNWRA QA program and its implementation. Eighteen applicable QA programmatic areas and seven technical areas were audited. The technical areas included: 1) Licensing Support Network; 2) Container Life and Source Term; 3) Repository Design and Thermal Mechanical Effects; 4) Mixed-Oxide Fuel Fabrication Facility Technical Assistance; 5) Reuse Soil Scenario Analysis; 6) Integrated Issue Resolution Status Report; and 7) Total System Performance Assessment and Technical Integration. This report addresses the effectiveness of the audit and the procedural adequacy and effectiveness of implementation of QA programs controls in the audited areas.

2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate whether the implementation of QA controls, associated with CNWRA QA programmatic and technical activities, met the applicable requirements of Appendix B to Title 10, U. S. Code of Federal Regulations (10 CFR), Part 50, as required by its contract with NRC. The NRC staff's objectives were to determine: 1) if the audit was performed in such a manner as to provide confidence in the CNWRA audit process and 2) whether CNWRA staff were adequately implementing QA program requirements specified in the CNWRA Quality Assurance Manual (CQAM), thus meeting contractual QA requirements.

3.0 SUMMARY AND CONCLUSIONS

The NRC observers' evaluation of the audit process and the CNWRA QA program was based on: 1) discussions with and direct observations of: a) the auditors and technical specialists of the audit team and b) CNWRA staff being audited; and 2) reviews of pertinent audit documentation such as the audit plan, the audit checklist, and other CNWRA documents.

The NRC observers determined that CNWRA Audit 2002-1 achieved its purpose of evaluating the implementation of the QA controls of programmatic and technical activities. The audit team was qualified and familiar with the QA requirements of the CNWRA program. The audit was conducted in a professional manner. The audit schedule and individual assignments were adequately described in the audit plan, and the audit checklist was detailed and complete.

The audit team identified two major deficiencies, one minor deficiency, and three isolated incidents which were corrected during the audit. All the findings were discussed with CNWRA management during daily debriefs and at the post-audit meeting.

In general, the observers agreed with the audit team findings that the CNWRA Quality Assurance Program is being effectively implemented and appears to provide effective controls

for technical product development. The audit team also indicated that the deficiencies identified during the audit are unlikely to have adverse impacts on the technical products.

4.0 AUDIT PARTICIPANTS

The audit team was staffed with NQA-1 qualified lead auditors and auditors from the Southwest Research Institute (SwRI) QA Department and by technical specialists from SwRI and a local university. The lead auditor, auditors, and technical specialists were independent of the activities audited, technically qualified, and trained in auditing techniques. In each case, a sub-team of a Technical Specialist and a QA Auditor performed the audit of each technical activity.

4.1 Nuclear Regulatory Commission Observers

Ted Carter	Observer (Team Leader -NRC)
James Pearson	Observer (QA Specialist - NRC)
Tamara Bloomer	Observer (Technical Specialist - NRC)
David Esh	Observer (Technical Specialist -NRC)
Deborah DeMarco	Observer (CNWRA Deputy Program Manager -NRC)

4.2 Audit Team

Robert Brient,	Audit Team Leader	SwRI
Thomas Trbovich	QA Auditor	SwRI
Rodney Weber	QA Auditor	SwRI
Mike Enright	Technical Specialist	SwRI
Steve Hudak	Technical Specialist	SwRI
John Hageman	Technical Specialist	SwRI
William Thomann	Technical Specialist	University of the Incarnate Word
Alex Bernardo	Technical Specialist	SwRI
Aaron DeWispelare	Technical Specialist	SWRI
Bob Mason	Technical Specialist	SWRI

5.0 CONDUCT OF THE AUDIT AND OBSERVATION

The CNWRA audit was conducted in accordance with CNWRA Quality Assurance Procedure (QAP)-011, "Audits." The NRC staff's observation of the CNWRA audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989 (Draft).

5.1 Scope of the Audit

The audit evaluated the CNWRA QA program to determine whether it meets the applicable requirements of Title 10, U. S. Code of Federal Regulations (10 CFR) Part 50, Appendix B. Such evaluation was accomplished by verifying the QA program implementation and effectiveness. The audit was performance-based and evaluated programmatic requirements in light of their application to technical activities. In addition, the corrective action process was reviewed to determine its effectiveness.

5.1.1 QA Programmatic Elements

<u>10 CFR Part 50, Appendix B, Criteria</u>		<u>CQAM Chapter</u>
I	Organization	1
II	QA Program	2
III	Design Control	N/A
	Scientific Investigation and Analysis Control	3
IV	Procurement Document Control	4
V	Instructions, Drawings, and Procedures	5
VI	Document Control	6
VII	Control of Purchased Material	7
VIII	Identification and Control of Items	8
IX	Control of Special Processes	9
X	Inspection	10
XI	Test Control	11
XII	Control of Measuring and Test Equipment	12
XIII	Handling, Storage, and Shipping	13
XIV	Inspection Test and Operating Status	14
XV	Nonconformance Control	15
XVI	Corrective Action	16
XVII	Records Control	17
XVIII	Audits	18

5.1.2 Technical Areas

The technical and programmatic areas selected for audit were determined by the Audit Team Leader and the CNWRA QA Director. The determination was made based on the level of activity, technical risks involved, programmatic risks involved, and the time since each area had last been audited. Since design-related activities are not performed by the CNWRA, criterion III of 10CFR Part 50, Appendix B, is not applicable to this audit.

A performance-based approach was used by the auditors during the audit to evaluate the effectiveness of the QA program in ensuring product quality. The auditors used direct evaluation of selected activities, assessment of products, and evaluations of product development processes. The performance-based approach was implemented by the use of teams composed of programmatic auditors and technical specialists evaluating activities from their individual perspectives, as well as evaluating implementation of procedures and plans associated with product development. The following areas were selected for this audit:

- 1) Licensing Support Network (LSN)
- 2) Container Life and Source Term (CLST)
- 3) Repository Design and Thermal Mechanical Effects (RDTME)
- 4) Mixed-Oxide Fuel Fabrication Facility Technical Assistance (MOX)
- 5) Reuse Soil Scenario Analysis (RSSA)
- 6) Integrated Issue Resolution Status Report (IIRSR)
- 7) Total System Performance Assessment and Technical Integration (TSPA&I)

5.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team was well-prepared and demonstrated a sound knowledge of the CNWRA program. The auditors and technical specialists used the checklist effectively during discussions with CNWRA personnel and review

of documents. The audit plan was thorough in describing the scope of the audit. Based on the length of time required during the audit for the CLST area, the NRC staff recommends that consideration be given to re-allotment of time for similar areas during the next audit to allow for the audit process to be thoroughly implemented without interruption.

The audit team and the NRC observers caucused at the end of the day. Also, a meeting of the audit team, observers, and CNWRA management was held each morning to discuss the current audit status and preliminary findings. In general the NRC staff believes the timing of the audit was appropriate.

5.3 Audit Team Qualification and Independence

The QA audit team was staffed with auditors from the SwRI QA Department and lead auditors qualified to the CNWRA QA manual. The qualifications of the Audit Team Leader and the audit team members were found to be acceptable in that each met the requirements of SwRI procedure No. NQAP 2.0-1, "Qualification and Certification of QA Auditors," dated November 1989. A sub-team of a Technical Specialist and a QA Auditor performed each technical audit activity and used the checklist to cover the subject matter well. The team members had no involvement with, or responsibility for, performing any of the activities they audited.

5.4 Examination of QA Programmatic and Technical Activities

CNWRA Audit 2002-1 was conducted as a performance-based audit. The audit team focused on the technical activities and evaluated the QA programmatic controls applicable to those activities. The NRC staff observed that each of the auditors reviewed related documentation and interviewed a representative sample of CNWRA personnel to determine their understanding of implementing procedures and processes. Checklists were used effectively, and issues were provided, beyond the checklists, when appropriate. The NRC observers were provided ample opportunities to provide comments and ask questions.

The audit of all of the above seven technical areas listed in section 5.1.2 was performed. Out of the seven technical areas audited by the audit team, all were observed by the observation team, with the exception of RSSA and IIRSR.

Training, education, and experience records were reviewed for personnel conducting scientific studies, to ensure such personnel were in compliance with their individual position descriptions. Objective evidence was provided to, and reviewed by, the audit team, and it was determined that all personnel were in compliance.

During the audit, the audit team identified deficiencies in the program, which resulted in two deficiencies in the areas of justification of assumptions and verification of calculations and one deficiency dealing with inconsistency in the frequency for trending adverse conditions. These findings were discussed with CNWRA management at the post-audit meeting.

The audit was effective in determining CNWRA compliance with procedural controls in the areas examined. The audit was thorough and effective in determining CNWRA personnel knowledge of, and compliance with, procedural controls. The NRC staff agrees with the audit team's assessment that, overall, the CNWRA is acceptably implementing its QA program.

6.0 NRC STAFF FINDINGS AND RECOMMENDATIONS

The QA programmatic and technical portions of the audit were conducted in a professional manner and the audit team adequately evaluated activities and objective evidence. The Audit Team Leader was effective in his daily presentation to the CNWRA management and staff and provided guidance to the audit team. Both the auditors and CNWRA staff were knowledgeable in their respective disciplines. The checklist was an excellent tool for providing a sound basis from which to conduct the performance-based audit. The NRC observers believed that the CNWRA audit was thorough and effective. They determined that the audit was effective in determining CNWRA compliance with procedural controls in the areas examined and that the CNWRA QA program controls are being adequately implemented. The technical qualifications of CNWRA staff were satisfactory. The technical adequacy of the work products and procedures was found satisfactory and is subject to continuing in-depth evaluation by NRC technical staff. While the observers do not agree with all the audit team findings (see CLST under 6.1), overall the observers agree with the audit team's assessment that the CNWRA is implementing its QA program satisfactorily.

CNWRA Audit 2002-1 was conducted as a performance-based audit. The audit team focused on the technical activities and evaluated the QA programmatic controls applicable to those activities. Out of the seven technical areas audited by the audit team, all were observed by the observation team, with the exception of RSSA and IIRSR.

6.1 NRC Findings

License Support Network (LSN)

An interview with the LSN element manager indicated the significance of a high level of accuracy during the population of the LSN, as well as the remaining labor-intensive activity that will be required to accomplish the task. Responses to audit interview questions included some of the challenges of populating the network with multiple types of media and development of acceptable references to the physical samples that may be required for license support. Additional discussion included the high level of accuracy required for indexing the large volume of supporting documentation which will populate the LSN.

The following strengths were indicated during audit interviews with the ongoing work in this element. 1) A good relationship with NRC counterparts allows frequent and candid interactions, 2) CNWRA staff are able to raise and resolve issues with NRC in a timely fashion.

Two technical suggestions were offered during the audit: 1) Develop a documented string of plans that provide continuity from the operations plan to products for the staff. 2) Develop a high-level process description of how LSN issues are established and resolved to support long-term external visibility into the LSN.

The observers agreed with the audit team's findings and recommendations.

Container Life Source Term (CLST)

The audit team reviewed two CNWRA deliverables in the CLST area; the first was Intermediate Milestone 01402.571.210, "Evaluation of Analogs for Performance Assessment of High-Level Waste Container Materials" (CNWRA 2002-02); and the second was Intermediate Milestone

01412.571.170, "Effect of Environment on the Corrosion of Waste Package and Drip Shield Materials" (CNWRA 2001-3).

The audit team found that overall the report preparation and review process were adequate, and that the reports had well thought-out technical approaches (such as long-term verification to confirm short-term experiments). The audit team's review of several scientific notebooks from the CLST laboratories found that compliance has improved over previous years. However, minor deficiencies were identified and corrected during the audit. The audit team considered this finding a minor nonconformance. The observers also reviewed several scientific notebooks and agreed with these findings.

The observers agreed with the audit team's assessment that the CNWRA is implementing its QA program in the procedure area.

The observers do not agree that the audit team's evaluation of the deliverable was appropriate. The audit team's evaluation of the deliverables led to several technical suggestions. The audit team explained that these findings are not considered as recommendations and no action is required by the CNWRA. However, the observer found that the questions during this part of the audit team's inspection appeared outside the scope of a quality program audit. The observers also found that the technical suggestions were more in the arena of a programmatic review and should not have been presented to the CNWRA. The observers discussed this concern with the audit team lead, while the questions were in progress, and with the audit team as a whole, when the suggestions were written during the daily caucus. In addition to the above concern, the observers suggested to the audit team, for future audits, that more time be allocated to the review of areas that incorporate laboratory investigations. The auditor only had time to review one scientific notebook within the time allotted for the CLST. One notebook is not necessarily a representative sample of all of the notebooks produced since the last audit.

Repository Design and Thermal Mechanical Effects (RDTME)

The audit team reviewed the processing and technical quality of several selected CNWRA deliverables in the RDTME area. These included "Mechanical Response of Drip Shields Under Repository Environment - Progress Report 2, Repository Design and Thermal-Mechanical Effects Key Technical Issue Intermediate Milestone No. 20.01402.671.240, November 2001"; "DECOVALEX III Task 2C: Thermal-Mechanical Modeling of the Drift-Scale Heater Test at Yucca Mountain - A Progress Report, December 2001"; and "Assessment and Process-Level Waste Package and Drip Shield Studies for Input to SEISMO Module of the TPA Code."

The audit team found that the deliverables had adequately met the QA requirements. Numerous positive practices were identified. An error was identified with an ASME code. A detailed discussion was provided in the deliverable, describing the error and why an earlier version of the ASME code was used. Scientific notebook reviews were being completed more frequently than required and also were being copied every 6 months, to reduce the risk of losing data. Software documentation was complete and readily available.

Two technical suggestions that resulted from the audit were to provide: (1) quantitative validation for a finite element model being used in some of the analyses, and (2) a broader range of temperatures in the evaluation of the mechanical response of the drip shields. The investigators had selected a pessimistic value (160 C) understanding that there could be significant variability in temperatures both temporally and spatially. It was difficult for the

investigators to select a more realistic value with associated uncertainty as a result of DOE's frequent changes to repository design.

The observers agreed with the audit team's findings and recommendations.

Mixed Oxide (MOX) Fuel Fabrication Facility Technical Assistance

The interview of the MOX element manager, during the audit, showed that the project was well in control. The additional conservatism, noted through the use of criteria based on NRC documents for nuclear power plant licensing during the review process, was identified as a good practice. No scientific notebooks were initiated nor were any calculations performed in regard to the MOX final review plan; therefore none were available for review during the audit.

The observers agreed with the audit team's findings and recommendations.

Total System Performance Assessment and Technical Integration (TSPA&I)

The audit team reviewed the processing and technical quality of several selected CNWRA deliverables in the TSPA area: These included (1) "Response to the External Peer Review of the Total-System Performance Assessment Version 3.2 Code, September 2001", "Transmittal of revised version of the Total-System Performance Assessment and Integration Issue Resolution Blueprint - Letter Report," April 5, 2002, and "Software Requirements Description for the TPA Version 5.0 Code, December 2001."

The audit team found that the deliverables were thorough and detailed. The software requirements document provided a good description of the requirements for modifications to the TPA code. Review packages were evaluated and were found to include comprehensive comments from the technical and programmatic reviewers.

Two deliverables contributed to major deficiencies. First, the TSPA issue resolution blueprint letter report contained inadequate and inconsistent referencing. CQAM section 3.3.10 "Data Interpretation and Analysis" requires that a technically qualified person may review, understand, and verify the analysis without recourse to the originator (including references). It was determined that QAP-002, instructions to technical reviewers, does not convey the full scope of the requirements identified in CQAM 3.3.10. Second, the review package for the response to the external peer review deliverable did not provide information on how sample (calculation) verification was accomplished, nor the conclusions regarding the calculation accuracy. The audit team determined that QAP-002, "Instructions to Technical Reviewers," does not provide for the specification of the extent and type of over-checks, and does not instruct the reviewer regarding the level of documentation required for verification. It was discussed and accepted that the intent of the requirements was for technical reviewers to produce objective information documenting calculation verification.

The response to the external peer review for TPA version 3.2 was developed to address formally elicited comments from a group of experts. The original comments from the experts were in some cases written verbatim, in other cases paraphrased, and sometimes combined with other comments. The report was developed providing a response to the extracted comment with a link to the original text (located in an appendix). The response to the comments was traceable when proceeding from the response to the experts' original comments. However, it was very difficult for an independent reviewer to proceed from the experts' original comments to a specific response. Therefore it was very difficult to verify that all the concerns presented by the experts had been adequately addressed. A technical

suggestion was made to provide for clear accounting of all comments and their resolution (consider using cross-walk tables) in a future revision to the document.

The observers agreed with the audit team's findings and recommendations.

6.2 NRC Recommendations

The following three recommendations are made by the observers:

- Based on the length of time required during the audit for the CLST area, the NRC staff recommend that consideration be given to re-allotment of time for similar areas next audit to allow for the audit process to be thoroughly implemented without interruption.
- The observers found that most of the audit team questions based in the CLST deliverables appeared outside the scope of a quality program audit. The NRC staff recommends that further guidance be provided to the audit team in preparing check list to ensure that questions are appropriate QA audit.
- When an analyst/scientist is going to leave CNWRA (because of the end of his/her term of employment there), the appropriate CNWRA personnel should thoroughly review all work the departing analyst/scientist did on NRC projects, and also verify if it was completed accurately. Assumptions the analyst/scientist made, regarding the project(s) should also be reviewed, if possible, before his/her departure.